Remarks

Claims 1 and 41 have been amended with the details set forth in Attachment I (Version with Markings to Show Changes Made).

The 35 USC 103 Rejections

Claims 1-3, 5-7, and 9 are rejected under 35 USC 103(a) as unpatentable over Pyle et al. Pyle et al teaches a method including steps of:

- 1. passing a microbial sample through a collecting device to capture the cells,
- 2. adding to the collecting device a fluorochrome dye specific for the detection of respiring cells and allowing the dye to incubate,
- 3. treating the collecting device with a reactive fluorescent antibody which reacts with a target micro-organism of interest present in said microbial sample,
- 4. mounting the collecting device for examination by fluorescence microscopy in which a suitable light system is used to excite the fluorochrome dye and fluorescent antibody to fluoresce, and
 - 5. quantifying the respiring cells.

Claim 1, for example, sets forth a sequence of seven(7) operational steps for carrying out the claimed "method for pathogen detection". The Examiner admits that Pyle et al fails to touch or suggest the claimed step of adding the fluorescent labeled antibodies... Thus, the Examiner is called upon to explain how the five(5) operational step of the method of this reference teaches or suggests, either expressly or impliedly, the seven(7) operational steps set forth in Claim 1. In addition, where in the reference is

taught the additional features of Claims 3, 5-7, and 9? As previously argued, the "attaching" and "inserting" operational steps of Claim 1 are not found in the reference, contrary to the Examiner's contention otherwise.

Since the features recited in these so rejected, claims are not taught or suggested, as required to support a rejection thereof under 35 USC 103, this rejection should be withdrawn.

Claims 1, 4-6, and 8-9 are rejected under 35 USC 103(a) as unpatentable over Marshall in view of Okusa et al. The Examiner admits that Marshall does not teach or suggest the filter material (substrate) is on a dipstick, and as previously pointed out, these references fail to teach of suggest "attaching the microbeads to a disposable capture substrate" and "inserting the substrate in an optical detection system" as recited in Claim 1. Since the teachings of the applied references, when taken as a whole, fail to teach or suggest claimed features, such fail to support a rejection thereof under 35 USC 103. Accordingly, this rejection should be withdrawn.

Claims 1 and 36-38 are rejected under 35 USC 103(a) as being unpatentable over Pyle et al. It is noted that this is the second rejection of Claim 1 on this same reference. Claims 36-38 depend from Claim 1. As pointed out above, this reference fails to teach or suggest the features of parent Claim 1, and thus fials to support or rejection of Claims 36-38. The rejection should be withdrawn.

Claims 1 and 39-40 are rejected under 35 USC 103(a) as unpatentable over Pyle et al in view of Wang et al. As pointed out above, the reference Pyle et al fails to teach or suggest the features of parent Claim 1, and the reference Wang et al fails to teach the features lacking in the primary reference. Thus, this ground of rejection should be withdrawn.

Claims 41-43 are rejected under 35 USC 103(a) as unpatentable over Marshall in view of Okusa et al. Where in this combination of references is taught or suggested the six (6) operational steps of Claim 41, or the additional "forming" operation of Claim

42, or the "decoding" feature of Claim 43? When the combined teaching of the reference fails to teach the feature recited in the claims rejected thereon, the references fail to support a rejection of such claims. Thus, this rejection should be withdrawn.

Conclusion

In view of the amendments to the claims and the foregoing comments, these rejections are improper and should be withdrawn. This application is deemed to be allowable based on Claims 1-9 and 36-43.

Respectfully submitted,

Dated: <u>/-/4-03</u>

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Enclosure:

Attachment I

Attachment I S.N. 09/880,515 Version with Markings to Show Changes Made



In The Claims:

Claims 1 and 41, amend to read as follows:

1. (Twice Amended) A method for pathogen detection <u>composed of sequential</u> <u>operations</u> comprising:

containing optically encoded microbeads,

adding a sample and capture ligand to the contained microbeads,

placing the contained microbeads in a mixing holder for sufficient time for a targeted biological sample to adequately bind the microbeads,

adding fluorescent labeled antibodies for attachment to the microbead bound sample,

attaching the microbeads to a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto,

washing the substrate and attached microbeads, and

inserting the substrate into an optical detection system for optically decoding the microbeads for identification and measurement of the target biological sample.

41. (Amended) A method for pathogen detection <u>composed of sequential</u> <u>operations</u> comprising:

containing a quantity of microbeads,

adding a sample and capture legend to the contained microbeads,

adding fluorescent labeled antibodies for attachment to a microbead bound

sample,

providing a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto,

inserting the disposable capture substrate containing the array of attachment sites into the contained microbeads for capturing the microbeads, and

inserting the disposable capture substrate into a detection system for decoding the microbeads for identification and measurement of biological molecules attached to the microbeads.